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Elaine C. Stracker

## PATENT

Attorney's Docket No.: 00021.06CON

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Rabinowitz et al.

Serial No.: 10/749,783

Filed: 12/30/2003

Title DELIVERY OF DRUG ESTERS THROUGH AN INHALATION  
ROUTE

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
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## INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In accordance with their continuing duty of disclosure under 37 CFR §§ §1.97, 1.98 and 1.56, Applicants hereby submit for consideration in the above-identified application the enclosed references. The Information Disclosure statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

For the convenience of the Examiner, the references are listed on a PTO Form 1449 (attached) and copies thereof are enclosed. Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

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Elaine C. Stracker J.D., Ph.D., Reg. 43,166

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# TRANSMITTAL FORM

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Total Number of Pages in This Submission

Application Number	10/749,783
Filing Date	12/30/2003
First Named Inventor	Joshua D. Rabinowitz
Art Unit	Not yet known
Examiner Name	To be assigned
Total Number of Pages in This Submission	Attorney Docket Number 00021.06CON

## ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Group
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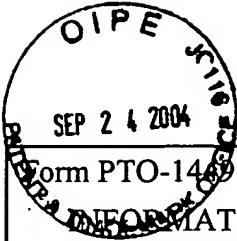
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SEP 24 2004

Form PTO-1469

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

Docket Number:	00021.06CON	Application Number:	10/749,783
Applicant:	Joshua D. RABINOWITZ, et al.		
Filing Date:	12/30/2003	Group Art Unit:	Not Yet Known

## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	01/05/1965	3,164,600	Janssen			
	2.	02/02/1971	3,560,607	Hartley et al.			
	3.	03/15/1983	4,376,767	Sloan			
	4.	12/27/1983	4,423,071	Chignac et al.			
	5.	07/08/1985	3,894,040	Buzby, Jr.			
	6.	03/31/1987	4,654,370	Marriott, III et al.			
	7.	07/18/1989	4,848,374	Chard et al.			
	8.	01/23/1990	4,895,719	Radhakrishnun et al.			
	9.	04/17/1990	4,917,120	Hill			
	10.	09/17/1991	5,049,389	Radhakrishnun			
	11.	05/12/1992	5,112,598	Biesalski			
	12.	06/30/1992	5,126,123	Johnson			
	13.	02/14/1995	5,388,574	Ingebrethsen			
	14.	08/13/1996	5,544,646	Lloyd et al.			
	15.	03/04/1997	5,607,691	Hale et al.			
	16.	04/22/1997	5,622,944	Hale et al.			
	17.	12/09/1997	5,694,919	Rubsamen et al.			
	18.	04/07/1998	5,735,263	Rubsamen et al.			
	19.	04/14/1998	5,738,865	Baichwal et al.			
	20.	06/29/1999	5,915,378	Lloyd et al.			
	21.	08/10/1999	5,934,272	Lloyd et al.			
	22.	09/28/1999	5,957,124	Lloyd et al.			
	23.	10/05/1999	5,960,792	Lloyd et al.			
	24.	11/30/1999	5,993,805	Sutton et al.			
	25.	03/28/2000	6,041,777	Faithfull et al.			

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Form PTO-1449  INFORMATION DISCLOSURE CITATION IN AN APPLICATION  <i>(Use several sheets if necessary)</i>		Docket Number: 00021.06CON	Application Number: 10/749,783
		Applicant: Joshua D. RABINOWITZ, et al.	
		Filing Date: 12/30/2003	Group Art Unit: Not Yet Known

26.	04/18/2000	6,051,566	Bianco			
27.	08/01/2000	6,095,153	Kessler et al.			
28.	08/15/2000	6,102,036	Slutsky et al.			
29.	06/05/2001	6,241,969	Saidi et al.			
30.	07/03/2001	6,255,334	Sands			
31.	10/08/2002	6,461,591	Keller et al.			
32.	01/14/2003	6,506,762	Horvath et al.			
33.	02/04/2003	6,514,482	Bartus et al.			
34.	07/15/2003	6,591,839	Meyer et al.			
35.	09/06/2001	US 2001/0020147	Staniforth et al.			
36.	03/28/2002	US 2002/0037828	Wilson et al.			
37.	05/16/2002	US 2002/0058009	Bartus et al.			
38.	07/04/2002	US 2002/0086852	Cantor			
39.	08/22/2002	US 2002/0112723	Schuster et al.			
40.	11/28/2002	US 2002/0176841	Barker et al.			
41.	01/02/2003	US 2003/0004142	Prior et al.			
42.	02/13/2003	US2003/0032638	Kim et al.			

## RELATED ALEXZA MOLECULAR DELIVERY CORPORATION PATENT DOCUMENTS

43.	08/04/2003	10/633,876	Hale et al.			
44.	08/04/2003	10/633,877	Hale et al.			
45.	12/30/2003	10/749,537	Rabinowitz et al.			
46.	12/30/2003	10/749,539	Rabinowitz et al.			
47.	01/27/2004	10/766,149	Rabinowitz et al.			
48.	01/27/2004	10/766,279	Rabinowitz et al.			
49.	01/27/2004	10/766,566	Rabinowitz et al.			
50.	01/27/2004	10/766,574	Rabinowitz et al.			
51.	01/27/2004	10/766,634	Rabinowitz et al.			
52.	01/27/2004	10/766,647	Rabinowitz et al.			
53.	01/28/2004	10/767,115	Rabinowitz et al.			

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		Applicant: Joshua D. RABINOWITZ, et al.			
		Filing Date: 12/30/2003		Group Art Unit: Not Yet Known	

54.	01/29/2004	10/768,205	Rabinowitz et al.			
55.	01/29/2004	10/768,220	Rabinowitz et al.			
56.	01/29/2004	10/768,281	Rabinowitz et al.			
57.	01/29/2004	10/768,293	Rabinowitz et al.			
58.	01/30/2004	10/769,046	Rabinowitz et al.			
59.	01/30/2004	10/769,051	Rabinowitz et al.			
60.	01/29/2004	10/769,157	Rabinowitz et al.			
61.	01/29/2004	10/769,197	Rabinowitz et al.			
62.	02/09/2004	10/775,583	Rabinowitz et al.			
63.	02/09/2004	10/775,586	Rabinowitz et al.			
64.	03/03/2004	10/791,915	Hale et al.			
65.	03/03/2004	10/792,001	Rabinowitz et al.			
66.	03/03/2004	10/792,012	Hale et al.			
67.	03/03/2004	10/792,013	Rabinowitz et al.			
68.	03/03/2004	10/792,096	Hale et al.			
69.	03/03/2004	10/792,239	Hale et al.			
70.	03/31/2004	10/813,721	Rabinowitz et al.			
71.	03/31/2004	10/813,722	Rabinowitz et al.			
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74.	04/01/2004	10/815,527	Rabinowitz et al.			
75.	04/01/2004	10/816,407	Rabinowitz et al.			
76.	04/01/2004	10/816,492	Rabinowitz et al.			
77.	04/01/2004	10/816,567	Rabinowitz et al.			
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79.	01/23/2003	US 2003/0015196	Hodges et al.			
80.	04/03/2003	US 2003/0062042	Wensley et al.			
81.	11/13/2003	US 2003/0209240	Hale et al.			
82.	01/02/2003	US 2003/0000518	Rabinowitz et al.			
83.	01/09/2003	US 2003/0005924	Rabinowitz et al.			

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				Applicant: Joshua D. RABINOWITZ, et al.			
				Filing Date: 12/30/2003		Group Art Unit: Not Yet Known	
	84.	01/09/2003	US 2003/0005925	Hale et al.			
	85.	01/09/2003	US 2003/0007933	Rabinowitz et al.			
	86.	01/09/2003	US 2003/0007934	Rabinowitz et al.			
	87.	01/16/2003	US 2003/0012737	Rabinowitz et al.			
	88.	01/16/2003	US 2003/0012738	Rabinowitz et al.			
	89.	1/16/2003	US 2003/0012740	Rabinowitz et al.			
	90.	01/23/2003	US 2003/0015189	Rabinowitz et al.			
	91.	01/23/2003	US 2003/0015190	Rabinowitz et al.			
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	93.	01/23/2003	US 2003/0017115	Rabinowitz et al.			
	94.	01/23/2003	US 2003/0017116	Rabinowitz et al.			
	95.	01/23/2003	US 2003/0017117	Rabinowitz et al.			
	96.	01/23/2003	US 2003/0017118	Rabinowitz et al.			
	97.	01/23/2003	US 2003/0017119	Rabinowitz et al.			
	98.	01/23/2003	US 2003/0017120	Rabinowitz et al.			
	99.	1/30/2003	US 2003/0021753	Rabinowitz et al.			
	100.	01/30/2003	US 2003/0021754	Rabinowitz et al.			
	101.	01/30/2003	US 2003/0021755	Hale et al.			
	102.	02/20/2003	US 2003/0035776	Hodges et al.			
	103.	05/15/2003	US 2003/0091511	Rabinowitz et al.			
	104.	05/27/2004	US 2004/010148	Hale et al.			
	105.	07/31/2003	US 2003/0138382	Rabinowitz			
	106.	11/06/2003	US 2003/0206869	Rabinowitz et al.			
	107.	01/15/2004	US 2004/0009128	Rabinowitz et al.			
	108.	05/20/2004	US 2004/0096402	Hodges et al.			
	109.	05/27/2004	US 2004/0099269	Hale et al.			
	110.	06/03/2004	US 2004/0105818	Hale et al.			
	111.	06/03/2004	US 2004/0105819	Hale et al.			
	112.	07/01/2004	US 2004/0126326	Rabinowitz et al.			
	113.	07/01/2004	US 2004/0126327	Rabinowitz et al.			
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		Applicant: Joshua D. RABINOWITZ, et al.			
		Filing Date: 12/30/2003		Group Art Unit: Not Yet Known	

	114.	07/01/2004	US 2004/0126328	Rabinowitz et al.			
	115.	07/01/2004	US 2004/0126329	Rabinowitz et al.			
	116.	07/01/2004	US 2004/0127481	Rabinowitz et al.			
	117.	07/01/2004	US 2004/0127490	Rabinowitz et al.			
	118.	08/12/2004	US 2004/0156788	Rabinowitz et al.			
	119.	08/12/2004	US 2004/0156789	Rabinowitz et al.			
	120.	08/12/2004	US 2004/0156791	Rabinowitz et al.			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	121.	11/11/1981	EP 0 039 369	Europe			
	122.	03/14/1990	EP 0 358 114	Europe			
	123.	07/03/2001	EP 1 080 720	Europe			
	124.	08/29/2001	EP 0 606 486	Europe			
	125.	02/14/1985	WO 85/00520	WIPO			
	126.	04/11/1996	WO 96/09846	WIPO			
	127.	05/09/1996	WO 96/13161	WIPO			
	128.	05/09/1996	WO 96/13290	WIPO			
	129.	05/09/1996	WO 96/13291	WIPO			
	130.	05/09/1996	WO 96/13292	WIPO			
	131.	10/03/1996	WO 96/30068	WIPO			
	132.	05/09/1997	WO 97/16181	WIPO			
	133.	08/07/1997	WO 97/27804	WIPO			
	134.	05/28/1998	WO 98/22170	WIPO			
	135.	07/23/1998	WO 98/31346	WIPO			
	136.	08/27/1998	WO 98/36651	WIPO			

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				Filing Date:	12/30/2003
				Group Art Unit:	Not Yet Known

137.	09/03/1998	WO 98/37896	WIPO		
138.	12/16/1999	WO 99/64094	WIPO		
139.	01/06/2000	WO 00/00176	WIPO		
140.	01/06/2000	WO 00/00215	WIPO		
141.	05/18/2000	WO 00/27363	WIPO		
142.	05/25/2000	WO 00/28979	WIPO		
143.	05/25/2000	WO 00/29053	WIPO		
144.	09/17/2000	WO 00/47203	WIPO		
145.	11/02/2000	WO 00/64940	WIPO		
146.	11/09/2000	WO 00/66084	WIPO		
147.	12/21/2000	WO 00/76673	WIPO		
148.	01/25/2001	WO 01/05459	WIPO		
149.	06/14/2001	WO 01/41732	WIPO		
150.	01/03/2002	WO 02/00198	WIPO		
151.	03/28/2002	WO 02/24158	WIPO		

#### OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	152.	Bennett, R.L. et al. (1981). "Patient-Controlled Analgesia: A New Concept of Postoperative Pain Relief," <i>Annual Surg.</i> 195(6):700-705.
	153.	Carroll, M.E. et al. (1990), "Cocaine-base smoking in rhesus monkeys: reinforcing and physiological effects," <i>Psychopharmacology (Berl.)</i> . 102:443-450.
	154.	Darquenne, C. et al. (1997). "Aerosol Dispersion in Human Lung: Comparison Between Numerical Simulations and Experiments for Bolus Tests," <i>American Physiological Society</i> . 966-974.
	155.	Davies, C.N. et al. (May 1972). "Breathing of Half-Micron Aerosols," <i>Journal of Applied Physiology</i> . 32(5):591-600.
	156.	Dershwitz, M., M.D., et al. (September 2000). "Pharmacokinetics and Pharmacodynamics of Inhaled versus Intravenous Morphine in Healthy Volunteers," <i>Anesthesiology</i> . 93(3): 619-628.
	157.	Finlay, W.H. (2001). "The Mechanics of Inhaled Pharmaceutical Aerosols", Academic Press: San Diego Formula 2.39. pp.3-14 (Table of Contents). pp. v-viii.

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		Applicant: Joshua D. RABINOWITZ, et al.	
		Filing Date: 12/30/2003	Group Art Unit: Not Yet Known

	158.	Gonda, I. (1991). "Particle Deposition in the Human Respiratory Tract," Chapter 176, <u>The Lung: Scientific Foundations</u> . Crystal R.G. and West, J.B. (eds.), Raven Publishers, New York. pp. 2289-2294.
	159.	Hatsukami D, et al. (May 1990) "A method for delivery of precise doses of smoked cocaine-base to humans." <i>Pharmacology Biochemistry &amp; Behavior</i> . 36(1):1-7.
	160.	Heyder, J. et al. (1986). "Deposition of Particles in the Human Respiratory Tract in the Size Range 0.005-15 µm," <i>J. Aerosol Sci.</i> 17(5):811-822.
	161.	Huizer, H., "Analytical studies on illicit heron. V. Efficacy of volatilization during heroin smoking." <i>Pharmaceutisch Weekblad Scientific Edition</i> (1987). 9(4):203-211.
	162.	Hurt, R.D., MD and Robertson, C.R., PhD, (October 1998). "Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial," <i>JAMA</i> 280(13):1173-1181.
	163.	Lichtman, A.H. et al. (1996). "Inhalation Exposure to Volatilized Opioids Produces Antinociception in Mice," <i>Journal of Pharmacology and Experimental Therapeutics</i> . 279(1):69-76.
	164.	Martin, B.R. and Lue, L.P. (May/June 1989). "Pyrolysis and Volatilization of Cocaine," <i>Journal of Analytical Toxicology</i> 13:158-162.
	165.	Mattox, A.J. and Carroll, M.E., (1996). "Smoked heroin self-administration in rhesus monkeys," <i>Psychopharmacology</i> , 125:195-201.
	166.	Meng, Y. et al. "Inhalation Studies With Drugs of Abuse," <i>NIDA Research Monograph</i> , (1997) 173:201-224.
	167.	Meng, Y., et al. (1999). "Pharmacological effects of methamphetamine and other stimulants via inhalation exposure," <i>Drug and Alcohol Dependence</i> . 53:111-120.
	168.	Office Action mailed 8/13/2003 for US application 10/153,313 filed 05/21/2002 "DELIVERY OF BENZODIAZEPINES THROUGH AN INHALATION ROUTE"
	169.	Pankow, J.F. et al. (1997). "Conversion of Nicotine in Tobacco Smoke to Its Volatile and Available Free-Base Form Through the Action of Gaseous Ammonia," <i>Environ. Sci. Technol.</i> 31:2428-2433.
	170.	Pankow, J. (March 2000). ACS Conference-San Francisco-3/26/00. Chemistry of Tobacco Smoke. pp. 1-8.
	171.	Seeman, J. et al. (1999). "The Form of Nicotine in Tobacco. Thermal Transfer of Nicotine and Nicotine Acid Salts to Nicotine in the Gas Phase," <i>J. Agric. Food Chem.</i> 47(12):5133-5145.
	172.	Sekine, H. and Nakahara, Y. (1987). "Abuse of Smoking Methamphetamine Mixed with Tobacco: 1. Inhalation Efficiency and Pyrolysis Products of Methamphetamine," <i>Journal of Forensic Science</i> 32(5):1271-1280.
	173.	Ward, M.E. MD, et al. (December 1997). "Morphine Pharmacokinetics after Pulmonary Administration from a Novel Aerosol Delivery System," <i>Clinical Pharmacology &amp; Therapeutics</i> 62(6):596-609.

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		Filing Date: 12/30/2003	Group Art Unit: Not Yet Known

174.	Wood, R.W. et al. (1996). "Generation of Stable Test Atmospheres of Cocaine Base and Its Pyrolyzate, Methylecgonidine, and Demonstration of Their Biological Activity." <i>Pharmacology Biochemistry &amp; Behavior</i> . 55(2):237-248.
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EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.